

**Remarks**

Claims 1-41 are pending the current application. Of these, claims 8, 13 and 18-41 are withdrawn from consideration. Claims 1-7, 9-12, and 14-18 are rejected.

**Claim Rejections - 35 U.S.C. §103**

The Examiner stated that claims 1-7, 9-12 and 14-18 were rejected under 35 USC §103(a) as being unpatentable over Kosal, U.S. Patent No. 6,545,086, in view of Gray et al., U.S. Patent No. 6,040,307, and further in view of Ulrich, U.S. Patent No. 6,365,146. This is basically the same ground of rejection as stated in the first Office Action.

During patent examination the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the applicant is entitled to the patent. However, when a *prima facie* case is made, the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability. In the absence of the establishment of a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. MPEP §2142. If, as a matter of law, the issue of obviousness is in equipoise, the applicant is entitled to the patent. *In re Oetiker*, *supra* (Plager, concurring).

In response to applicants' arguments concerning Kosal, the Examiner argued that while "some silicone fluids are lipophilic," others are not, and that because Kosal "broadly teaches" a silicone fluid, Kosal's teaching of the use of a volatile silicone fluid encompassed both lipophilic and non-lipophilic solvents, rendering the claimed subject matter obvious. As applicants will demonstrate, Kosal's "teachings" are deficient and fail to meet the evidentiary burden on the PTO. As Kosal, the primary reference is deficient, the secondary references fail to make up for these deficiencies, and the rejection fails.

*Kosal fails to teach or suggest an emulsion that is "substantially free of lipophilic solvent."*

***(a) Kosal's silence is not evidence of obviousness.***

Independent claim 1 recites a controlled-release composition for topical application to a substrate, said composition comprising an oil-in-water emulsion and an active agent incorporated into the oil-in-water emulsion. Independent claim 1 further recites that the oil-in-water emulsion is "substantially free of lipophilic solvent." The Examiner must concede that Kosal is silent concerning whether or not his volatile silicone solvent is lipophilic or not. Silence in a reference is not evidence of obviousness. *In re Burt*, 148 USPQ 548, 553 (CCPA 1966). The Examiner's logic concerning what Kosal fairly teaches is flawed. The Examiner is basically arguing that the less a reference teaches, the more that it teaches. This type of reasoning has been criticized before in the context of an obviousness determination. See, *In re Burt*, *supra* at 553, where the court stated:

The examiner noted that "nothing in Pattison suggests that polyalkylene-ether polymers of *over* 10,000 M.W. are impossible to prepare" and that appellants had "submitted no argument or exhibit showing the impossibility of preparing the 30,000 M.W. polymer" prior to appellants' invention. While those observations are undoubtedly true, we might add that neither do the references suggest that those polymers can be prepared. Silence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow.

***(b) A preponderance of the evidence requires more than simply a 50/50 possibility.***

Moreover, even accepting the Examiner's arguments to be true (which applicants do not), at best Kosal teaches the use of a volatile solvent that *may* or *may not* be lipophilic. That is, the Examiner still has not shown that *it is more likely than not* that Kosal teaches the use of a non-lipophilic solvent. Where the evidence is in equipoise, the Examiner has failed to carry his evidentiary burden of establishing a *prima facie* case. See, *In re Oetiker*, *supra*.

***(c) Kosal fails to teach a composition where lipophilic solvents are excluded.***

Finally, the Examiner, in referencing Kosal's so-called "broad" teaching, makes the assumption that Kosal uses either (or both) lipophilic or non-lipophilic solvents. However, what Kosal fails to teach or suggest is to refrain from the use of lipophilic solvents as claimed.

Applicants fail to appreciate the relevance of the Examiner's comment that "[a]s the claimed composition contains comprising language, it does not exclude the presence of non-lipophilic silicone fluids." That may be true, but it is irrelevant because the claims do exclude the presence of lipophilic solvents.

### ***Conclusion***

The Examiner has failed to establish by evidence or reasoning that any of the applied references that teach or suggest, either singularly or in combination, a controlled-release composition for topical application to a substrate comprising an oil-in-water emulsion that is substantially free of lipophilic solvent and formed by mechanical inversion of a water-in-oil emulsion. As a result, the rejection of independent claim 1 fails. Additionally, as claims 2-7, 9-12 and 14-18 depend directly or indirectly from independent claim 1, the rejection of these claims fails as well.

Applicants further note that the Examiner has stated that claim 1 is generic. Should a generic claim be allowed, applicants understand that the species election requirement will be withdrawn. Also, should the composition claims be allowed, applicants understand that the restriction requirement may be withdrawn and the non-elected method claims may be rejoined. Applicants hereby request that the restriction and species election requirements be withdrawn and that the withdrawn claims be re-joined and examined on their patentable merits. In light of the foregoing, applicants submit that all of the pending claims are in condition for allowance. Accordingly, reconsideration and allowance of those claims are earnestly solicited.

Respectfully submitted,  
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